

REMARKS

Responsive to the lack of unity determination imposed in the outstanding Official Action mailed on March 17, 2006, applicants provisionally elect Group I, drawn to a process for extracting transforming growth factor β (TGF- β) from a milk product, with traverse.

The grounds for traverse are that the Official Action fails to satisfy PCT Rules 13.1 and 13.2. PCT Rules 13.1 and 13.2 require that a proper lack of unity determination show a lack of a "special technical feature". According to PCT Rule 13.2, the expression "special technical features" shall mean those features which define a contribution which each of the claimed inventions considered as a whole makes over the prior art". Thus, PCT Rule 13.2 is art-based. A proper lack of unity determination would require the citation of a reference showing the "special technical feature". As the Official Action fails to provide such a citation, applicants believe that the lack of unity determination is improper as a matter of law.

Moreover, the extraction process for obtaining TGF- β and IGF-1 involves a number of technical features, i.e., (a) recovery of the basic fraction of milk by cationic exchange chromatography, and (b) eluting a hydroxyapatite column loaded with the basic fraction with an eluent with increasing salt concentration or pH. These steps together lead to the separation of a first fraction rich in TGF- β and a second fraction rich in

IGF-1. These common technical features define a contribution of the invention over the prior art. Indeed, separation techniques involving chromatography have been reported as achieving less efficient separation of these different growth factors, if achieving any separation of TGF- β and IGF-1 at all.

Thus, considering elution step (c) in claim 1 as involving two separate inventions does not properly interpret the claims. The elution step involves a single technical feature of applying a pH or salt gradient to the column and results in a better separation of both growth factors from other milk product components and from one another.

Groups III and IV are also linked to Groups I and II, and should also be considered to share a single general inventive concept under PCT rule 13.1. They share the special technical feature of a separation method as explained above.

Applicants also note that the International Examiner did not find a lack of unity of invention. Thus, despite having the benefit of the International Preliminary Examination Report, the Official Action fails to explain why the opposite approach is now being taken in the present application.

In view of the above, applicants respectfully request a search and examination of all the pending claims in their full scope.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

Philip Dubois
Philip Dubois, Reg. No. 50,696
745 South 23rd Street
Arlington, VA 22202
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

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